

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>HON. ROBERT B. KUGLER</b>

**AMENDED NOTICE TO TAKE VIDEOTAPED ORAL DEPOSITION**

TO: **Clem C. Trischler, Esq,**  
**PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP**  
**38<sup>TH</sup> Floor, One Oxford Centre**  
**Pittsburgh, Pennsylvania 15219**  
*Attorneys for Defendants Mylan Pharmaceuticals Inc. (hereinafter "Defendants").*

Please take notice that pursuant to Federal Rule of Civil Procedure 30, and other applicable Rules, including the Local Civil Rules, and the applicable Orders of the Court, Plaintiffs, by and through their counsel, will take the videotaped deposition of Derek Glover, Head of Global Quality, on March 9, 11, and 12, 2021, at 9:00 a.m. eastern standard time, and continuing until completion, at Pietragallo Gordon Alfano Bosick & Raspanti, LLP, 38<sup>th</sup> Floor, One Oxford Center, Pittsburgh, Pennsylvania 15219, via zoom, in accordance with the Fact Witness Deposition Protocol, Case Management Order #20, filed November 17, 2020 (Document 632). The deposition shall address the Federal Rule of Civil Procedure 30(b)(6) topics listed on Exhibit A attached. The witness shall produce the documents requested at Exhibit B, attached hereto, at least 5 days in advance of the deposition.

Pursuant to the meet and confer between the parties, a translator will not be provided.

**TAKING ATTORNEYS FOR PLAINTIFFS:**

JOHN DAVIS  
Slack Davis Sanger LLP  
6001 Bold Ruler Way, Ste 100  
Austin, TX 78746  
Telephone: 512-795-8686  
Fax: 512-795-8787  
[jdavis@slackdavis.com](mailto:jdavis@slackdavis.com)

The videotaped deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure.

February 22, 2021

**PLAINTIFFS' CO-LEAD COUNSEL**

By: /s/Ruben Honik, Esq.  
RUBEN HONIK, ESQ.  
Golomb & Honik, P.C.  
1835 Market Street, Ste. 2900  
Philadelphia, PA 19103  
Telephone: 215-327-9166  
[ruben@honiklaw.com](mailto:ruben@honiklaw.com)

**EXHIBIT A****30(B)(6) TOPICS**

*On behalf of Mylan Pharmaceuticals Inc.:*

*Testing*

4. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.

5. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's valsartan API, (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.

6. The testing performed by Mylan or its agents, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

7. The testing performed by Mylan or its agents to evaluate the purity and contents of recovered or recycled solvents provided by Lantech Pharmaceuticals.

8. The testing performed by any entity or person other than Mylan or its agents but known to Mylan, to evaluate the purity and contents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

9. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.

10. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's valsartan API (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan API for sale in the United States.

11. The chromatogram and mass spectrometry of other results for all testing by Mylan or its agents of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

12. The chromatogram and mass spectrometry or other results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of Mylan's finished dose (regardless of intended sale location) manufactured in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

13. Mylan's evaluation of the potential risks to the purity or contents of Mylan's API posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

14. Mylan's evaluation of the potential risks to the purity or contents of Mylan's finished dose posed or caused by solvents used during the manufacturing process (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

15. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

16. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of

Mylan's API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States.

17. The chromatogram and mass spectrometry results for all testing by Mylan or its agents of the solvents utilized in the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

18. The chromatogram and mass spectrometry results for all testing by any entity or person other than Mylan or its agents but known to Mylan, of the solvents utilized in the manufacture of Mylan's finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States.

19. The extent of the actual and potential nitrosamine contamination of Mylan's valsartan API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

*Quality Assurance and Quality Control Activities*

20. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

21. Mylan's Standard Operating Procedures ("SOPs"), policies or procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens,

general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture and contents of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant SOP's, policies, or procedures.)

22. Mylan's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Mylan's valsartan API (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)

23. Mylan's application of cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, in connection with the manufacture of Mylan's valsartan finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)

24. Mylan's SOPs/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, for procurement of recovered or recycled solvents, and selection of vendors to provide such services.

*Mylan's Communications with Finished Dose Customers and Downstream Customers*

36. Mylan's oral and written communications with its valsartan API Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan API.

37. Mylan's oral and written communications with its valsartan finished dose Customers (including vertically integrated facilities) or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Mylan's finished dose.

38. Mylan's oral and written statements to the finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan API.

39. Mylan's oral and written statements to finished dose manufacturers, wholesalers, retailers, and consumers with regard to the contents and purity of Mylan's valsartan finished dose.

*Compliance with cGMPs*

43. Mylan's compliance or non-compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents, as it relates to the manufacture, quality assurance, quality control, and sale of Mylan's API and finished dose (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)

44. The policies, practices, procedures and trainings for monitoring compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as

nitrosamines, and residual solvents, (regardless of intended sale location) in any facility that manufactured Mylan's valsartan API or finished dose for sale in the United States. (The parties to meet and confer to identify the relevant cGMPs.)

45. The policies, practices, procedures and trainings for monitoring material providers (such as Lantech Pharmaceuticals) and their compliance with cGMPs intended to prevent, detect, or act in response to any impurity or contamination, for example carcinogens, general toxic impurities (including genotoxic impurities) such as nitrosamines, and residual solvents. (The parties to meet and confer to identify the relevant cGMPs.)

## **EXHIBIT B**

### **DOCUMENT REQUESTS**

1. The most recent resume/Curriculum Vitae and LinkedIn profile for Derek Glover.
2. The complete production of Derek Glover's relevant custodial documents, including those maintained on personal computers or electronic devices, to the extent not produced prior.



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**CERTIFICATE OF SERVICE**

I hereby certify that on February 22, 2021, I caused the foregoing to be electronically filed with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/ David J. Stanoch  
DAVID J. STANOCH  
Kanner & Whiteley, L.L.C.  
701 Camp St.  
New Orleans, LA 70130  
Telephone: 504-524-5777